



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN RE APPLN. OF: SMITS et al.

SERIAL NO.:

09/600,732

FILED:

July 20, 2000

FOR:

PROCESS FOR THE MANUFACTURE OF CHICORY INULIN . . .

GROUP:

1637

EXAMINER:

SURYAPRABHA CHUNDURU

DOCKET: TIENSE RAFF.26

MAIL STOP APPEAL BRIEF - PATENTS Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

TRANSMITTAL LETTER APPELLANTS' REPLY BRIEF

Dear Sir:

In connection with the above-entitled matter, enclosed please find Appellants' Reply to the Examiner's Answer (in triplicate).

In the event there are any fee deficiencies or additional fees are payable, please charge them (or credit any overpayment) to our Deposit Account No. 08-1391.

Respectfully submitted,

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Serial No. 09/600,732 Docket No. TIENSE RAFF.26 TRANSMITTAL LETTER - APPELLANTS' REPLY BRIEF

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APPELLANTS' REPLY BRIEF UNDER 37 CFR 1.193 (b)

This Reply Brief is being filed in response to the new points of argument raised in the Examiner's Answer mailed March 4, 2004. Appellants respond to these new points of argument as follows:

I. Procedural Issues

- A. At the onset it is noted, with appreciation, that the Examiner has withdrawn the rejection of the claims under 35 USC § 112, second paragraph.
- B. Before considering the specific points raised in the Examiner's Answer, it is noted that the first nine pages of the Examiner's Answer essentially comprises verbatim the rejections raised in the final rejection. However, the Examiner also appears to suggest a § 112, first paragraph rejection, without expressly raising same, when the Examiner notes, in the last sentence of the paragraph bridging pages 9-10 of the Examiner's Answer: "The broad limitations recited in the instant claim 65 does (sic) not exclude any day in a year and overlaps

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with the periods taught by Van den Ende et al". Compare the last sentence in the paragraph bridging pages 12-13 of the Examiner's Answer: "Here, the unexpected result for cultivating chicory roots is not commensurate in scope with the independent claim 65, which comprises a range of cultivating periods which include any day in a year". Needless to say, if the Examiner wishes to raise a § 112, first paragraph rejection, he should have raised the rejection before now.

II. The continued rejection of the claims as obvious from the art is in error.

Neither Yamazaki et al., nor Van den Ende et al. directly relate to the essence of the present invention, i.e., of improving yield through cultivation techniques, and do not contain any disclosure or teaching pointing to the present invention. Accordingly, it is Appellants' position that neither Yamazaki et al., nor Van den Ende et al, taken alone or in combination, or taken with Van Loo et al., disclose or teach the present invention, or give any motivation to the skilled person that may lead to the present claimed invention. This position is detailed below.

Firstly, as to Yamazaki et al. (hereinafter Yamazaki), Yamazaki merely relates to the production of fructose syrup. In fact, Yamazaki essentially relates to <u>one aspect</u> of said production, namely the conversion of inulin into fructose (US '377, Abstract; Col.1, lines 5-8; Col. 10, lines 19-22). Further aspects of the invention disclosed by Yamazaki also relate only to the said process (US '377, Col. 10, lines 23-34).

The source material for the process of Yamazaki is an aqueous solution containing inulin, obtained by extraction of tubers of J. artichoke with water. Yamazaki also mentions that chicory roots and dahlia tubers may be used instead of tubers of J. artichoke for obtaining said aqueous solution of inulin (US '377, Col. 10, lines 36-40; Col. 10, line 58 to Col.11, line 4, and US '377, Col. 10, lines 58-68; Col. 121, lines 24-27). It is emphasized however that Yamazaki does not

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relate at all, to the <u>provision/cultivation</u> of tubers of J. artichoke or dahlia, or roots of chicory.

The only disclosures in Yamazaki regarding the sources of inulin as such, are merely generic, background disclosures, namely:

- that "J. artichoke, a native plant of Canada, grows well in colder climates (even in waste lands) and provides a high yield of inulin in its tubers" (US '377, Col. 12, lines 3-5)
- that "J. artichoke tubers can be efficiently produced and harvested in late October and ideally should be processed within a few months (inulin content declines with storage time) (US '377, Col. 12, lines 21-24),
- that "[While inulin from J. artichoke tubers is the preferred source according to the aspects of the invention,] the inulin may also be derived in a similar fashion, from the roots of chicory or dahlia" (US '377, Col. 12, lines 24-27).

So, Yamazaki does not deal at all with the provision of the source material for inulin extraction, but only provides, as general technological background, some non-specific information regarding the conventional cultivation of J. artichoke. Besides, since chicory and J. artichoke are different plant species, and considering the diversity in nature between plants belonging to a different species, diversity that may well reflect in a difference in requirements of the growing conditions, Appellants submit that Yamazaki does not provide an enabling disclosure about the cultivation of chicory.

Accordingly, Appellants submit that Yamazaki is silent regarding the aspect of the cultivation of chicory as source material for inulin or fructose production, and, furthermore, urge in particular, that Yamazaki does not contain an enabling disclosure or teaching or incentive regarding the cultivation, under non-conventional conditions, of chicory roots for inulin

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production as required by the claims on Appeal.

Van Den Ende et al., in Plant Physiol. (1996), (hereinafter VDE) does not supply the missing teachings to Yamazaki to achieve or render obvious the claims on Appeal. VDE essentially relates to a study of the inulin synthesizing and degrading effects of enzymes in chicory roots during growth, storage and forcing of the roots in view of the production of Belgian andives (Witloof). VDE does not relate to the cultivation of chicory for the production of inulin or hydrolysates of inulin such as oligofructose and fructose (see VDE, p. 44, left col., paragraph starting line 4 and 2nd half of last paragraph before "Materials and Methods", starting "This paper reports on....", and Summary, p. 43).

VDE in fact merely reports about a study of inulin metabolism in chicory roots cultivated and processed towards Belgian andives under conventional conditions (VDE, p. 44, left Col, paragraph starting line 3, and last paragraph "Plant material", and Summary, p. 43).

Apart from particulars concerning metabolism, in particular the evolution of inulin anabolism and catabolism under conventional conditions of growth, cold storage (at 1°C) and forcing (at 16°C) of the roots, the VDE study merely confirms conventional knowledge that inulin is synthesized in chicory roots during the growing season and starts already degrading (from mid-September) even before the end of the growing season (at about the end of October, which is marked by a cessation of the increase of the biomass of the chicory roots), and further degrades during harvesting, cold storage and forcing (Description p. 8, line 20 to p.9, line 7; VDE, p. 44, paragraph starting line 3; P.47, left column, last sentence; and Fig. 3, Fig.4 and Fig.5).

At most, VDE can be considered to teach that inulin synthesis, content and degree of

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polymerisation increases during a first part of the growing period of the chicory roots, that inulin production decreases and ceases already before the end of the growing period, and that inulin in the chicory roots begin to degrade before the end of the growing period and further degrade during cold storage (at $+1^{\circ}$ C), as well as during forcing (at $+16^{\circ}$ C) of the roots.

Accordingly, Appellants emphasize that VDE does not contain any teaching or suggestion about the possibility to cultivate chicory roots (in particular as source material for the production of inulin or inulin hydrolysates) partly or completely outside the conventional cultivation period as in the claims on Appeal. Appellants also emphasize that VDE does not contain any teaching or suggestion about the triggering of the FEH gene and its inulin degrading activity as a result of particular conditions, namely well-defined low-temperature conditions, nor does VDE contain any teaching or suggestion about the possibility that low temperature conditions that trigger the FEH gene may occur in an early stage of the growing period of the chicory roots without having negative effects on the cultivation of the chicory roots later on (e.g. on yield of roots and/or on inulin synthesis, content and DP).

So, indicating a decrease of inulin synthesis, content and DP after a certain growing period and even before the end of the growing period, at storage at low temperature (+1°C), and during forcing (at +16°C) of the roots, VDE in fact teaches away from the present invention according to which longer growing periods as well as well-defined low temperature conditions during a well-defined period of the cultivation of the chicory roots, are tolerated. VDE in fact teaches away to growing chicory roots under conditions where low temperatures (frost) may occur, and VDE does not teach or suggest that said low temperature conditions may occur (in a first part of the growing period), without having negative effects on the growing and yield of the

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chicory roots, without blocking inulin synthesis, and without provoking a decrease of inulin synthesis later on in the growing period that would ultimately reflect at harvest time in a lower inulin content and low DP. Furthermore, VDE clearly does not teach or suggest that a longer growing period of at least 150 days, preferably of at least 180 or 220 days, and even a growing period of a complete year, of chicory roots with good results as to inulin content and DP is possible, compared to the conventional growing period of maximum about 150 days.

Appellants emphasize that it was not known in the art and could not be derived from the prior art that, once growing chicory roots <u>have been exposed</u> to low temperature conditions in the early growing period (thus once the FEH inulin degrading activity <u>had been</u> triggered), the inulin synthesis, content and DP would nevertheless evolve well in the further growing period and even reach conventionally high levels, provided that in said further growing period the temperature does not descend again below the well-defined lower temperature conditions.

Accordingly, VDE does not contain any teaching about the possibility to cultivate chicory roots with good results as to yield of roots and inulin synthesis, content and DP, partially or completely outside the conventional cultivation and harvesting period. VDE contains neither motivation for the skilled person to consider the cultivation of chicory roots for the production of inulin under non-conventional conditions, nor could a skilled person expect on the basis of the teaching of VDE that chicory roots for the production of inulin could be cultivated under non-conventional conditions with a reasonable expectation of success.

With regard specifically to ¶ 11(ii) of the Examiner's Answer, Appellants emphasize that the time periods for seeding, growing, harvesting/ processing of the chicory roots disclosed by VDE only ranges from 98 days to 120-145 days (June 1- October 4th; June 1 -October 25th) (see

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Examiner's Answer, p.10, §1). This is a time period with a duration that is still within the conventional one (namely up to 150 days with seeding and harvesting in a period that is free from temperature conditions that trigger the FEH gene*) (* first frost typically occurs at the very end of October – early November in the concerned region of Belgium). Besides, the period described by VDE does not comply with the duration of the time period beginning with seeding on June 1 according to the present invention, which according to current claim 65 is at least 180 days, thus at least one month more than the period of DVE.

Furthermore, the disclosures by VDE about the results of the analyses of inulin synthesis/degradation and variation of DP, just confirm, as discussed above, conventional knowledge and do not provide any teaching that leads to the present invention. To the contrary, the results of the analyses indicating already a decrease of inulin content and DP in the later part of the growing season (no frost season yet; see: Examiner's Answer, p. 10, end of §1), indeed point away from the longer growing season requirement of claim 65.

As pointed out above, the seeding, growing, harvesting/storing /processing period according to the present invention may be much longer than the conventional period, and may even extend over a whole year, provided that the requirements as to time period of occurrence and temperature of the defined low temperature conditions, are fulfilled (see Description p. 24, line 33 to p. 25, line 18, in particular p. 25, lines 10-15).

It should furthermore be noted that the conventional period is excluded from claim 65 by the feature of the longer time periods for seeding-growing-harvesting/storing/processing chicory roots according to the invention. So, the possibility that a certain part of the claimed period overlaps with the conventional period, does not negate the non-obviousness of the claimed

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invention because the claimed period according to the present claimed invention extends over a conventional one, and claim 65 has to be considered as a whole.

It is thus clear that the Examiner has employed impermissible hindsight and has applied the teachings of the present application to the prior art to make out a case of obviousness. As noted supra, in spite of the long felt need (for economical and practical reasons) to have a cultivation-processing period for chicory roots for the manufacture of inulin that is longer than the conventional one, no solution to said need and economical problem was available prior to the filing date of the subject patent application (see Description p. 9, line 8 to p.10 line 2; p. 24, line 33 to p.25, line 24). Accordingly, the solution to said problems, provided by the present invention cannot be considered obvious for the skilled person. Where is the motivation for one skilled in the art to consider non-conventional cultivation of chicory roots as source material in a process for the manufacture of inulin and inulin hydrolysates? The question speaks for itself!

As to the Examiner's reliance on "In re Cruciferous Sprout Litigation", Appellants submit that said reliance is improper because the present invention is not the result of a mere routine optimization of conventional process parameters/conditions covering a known range, in order to come to an improvement of an existing process. Indeed, the present invention employs non-conventional process parameters/conditions, namely parameters/conditions which are not implicitly covered by the conventional process parameters/conditions, because they fall partly or completely outside the range of the conventional process parameters/conditions. Accordingly, routine optimization of the conventional process parameters/conditions for the cultivation of chicory roots as source material for the manufacture of inulin and inulin hydrolysates could not lead to the process parameters/conditions of the present invention that enable to cultivate chicory

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roots partly or completely <u>outside</u> conventional process parameters/conditions.

Accordingly, the fact that the chicory roots according to the present invention are seeded/grown/processed partially or wholly outside the conventional periods removes the present claimed subject matter from the application of "In re Cruciferous Sprout Litigation". Therefore, Appellants submit that the Examiner's reliance on "In re Cruciferous Sprout Litigation" for the subject invention and, accordingly that its citation is improper.

On the bottom paragraph on page 11 of the Examiner's Answer, the Examiner takes the position that the claims do not recite any non-conventional cultivating conditions for chicory inulin production. The Examiner is wrong when the features of the claims are taken as a whole. According to the present claimed invention, either (1) the seeding period may be non-conventional, or (2) when the seeding period falls within a conventional one, the growing period is not conventional (at least one month longer [as already indicated above]), and non-conventional low temperature conditions may occur during the first months of the non-conventional growing period. Accordingly, the whole of the claimed cultivating conditions for chicory roots as source material for the production of inulin and inulin hydrolysates is non-conventional.

In the paragraph at the top of page 12 of the Examiner's Answer, the Examiner argues that it is prima facie obvious to optimize the cultivating conditions not to fall in the low temperature conditions. As indicated above, VDE teaches that a <u>decrease</u> in inulin synthesis/content and DP begins before the end of the growing season and a long time before the occurrence of frost (e.g. already in the period from September 13 to mid-October; VDE, Fig. 3; p.47, Fig.4, left column, last sentence, and right column, 2nd half; p.48, right col. 2nd half). And, VDE also teaches that

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when chicory roots are forced (= kept at +16°C) also an important breakdown of inulin and accumulation of fructose occur (VDE, p.48 right column, last three lines [to p.49, left column, 1st §]).

VDE, though indicating a decrease of inulin synthesis/content and DP at low temperature, also indicates same at forcing conditions (temp. +16°C). Thus, the teaching of VDE is certainly not unequivocal, and VDE indeed discloses that low temperature conditions may not be the only, limiting parameter for the cultivation of chicory roots. Besides, Appellants point out that low temperature conditions in the cultivation of chicory roots in accordance with the present invention may occur in the first months of the seeding-growing period. Furthermore, the occurrence of low temperature conditions in said early part of the growing season has no permanent, negative effects on inulin synthesis/content and DP. This finding was not known and completely unexpected at the filing date of the subject patent application.

Thus, optimization of the cultivation conditions within the range of conventional conditions would not lead to the present invention. Furthermore, in view of the lack of teaching and any incentive, the evaluation of a cultivation and of processing conditions for the cultivation of chicory roots for inulin production outside the conventional conditions, would not be considered by the skilled person. Therefore, the whole of the cultivation and processing conditions of chicory roots according to the presently claimed invention are non-obvious in view of the prior art, and accordingly the Examiner's conclusion of prima facie obviousness as stated in the paragraph at the top of page 12 of the Examiner's Answer are clearly not justified and thus improper.

Moreover, Van Loo et al. (hereinafter Van Loo) also fails to supply the missing teachings

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and motiviation to Yamazaki and VDE to achieve or render obvious claim 65 or any of the claims, including specifically, claims 79-88 dependent thereon.

Van Loo et al. (hereinafter Van Loo) merely relates to a method for processing inulin, whereby an aqueous solution of a polydisperse saccharide composition comprising mono-, di-, oligo-, and polysaccharides, is fed in a metastable state into a chromatography column, and is eluted with warm water and separated into various fractions, thus providing a fraction of inulin that is free from saccharides of a degree of polymerisation of less than or equal to 2.

So, Van Loo is clearly not related at all to the essential aspect of the subject claimed invention, which involves cultivating chicory roots as source material for the manufacture of inulin or inulin hydrolysates under conditions that partly or completely fall outside conventional cultivation and harvesting conditions.

Finally, it is noted the Examiner's reliance on In re Clemens as set forth in the paragraph bridging pages 12-13 of the Examiner's Answer is likewise in error. As argued, above and as disclosed in the patent application, the unexpected results are not restricted to a part of the claimed range of process features (taken as a whole), but clearly apply to the entire scope of the claimed range of cultivation and processing conditions of chicory roots for the production inulin and inulin hydrolysates in accordance with the presently claimed invention.

In conclusion, neither Yamazaki nor VDE taken alone, nor taken in combination, or taken in combination with Van Loo, teach or suggest the present invention to the person skilled in the art. Therefore, the essence of the present invention, as claimed in claim 65, has to be considered non-obvious. Furthermore, the several claims depending from claim 65 or referring to it, also enjoy non-obviousness from current claim 65.

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CONCLUSION

In view of the foregoing, it is respectfully submitted that the Examiner's Final Rejection of the subject Application is in error, and it is requested that the Rejection be reversed in all respects.

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